

INNOVATIONS

A CLINICAL
EXCHANGE ON
ADVANCES IN
ORTHOPAEDICS

VOLUME 4

ISSUE 2

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- 05 CAOS Augmented Mechanical Instrumentation Provides Versatility and Improved Accuracy During Total Knee Arthroplasty
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ISSUE 2

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Innovations features the latest solutions to the challenges orthopaedic surgeons face. Part technical journal and part clinician magazine, this publication facilitates surgeon-to-surgeon exchange on the tools and techniques that can improve patient outcomes.

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INNOVATION: VALIDATION: MEANINGFUL IMPROVEMENTS



 **Gary Miller, PhD**

Exactech Executive Vice
President, Research and
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Do you enjoy reading *Innovations*?

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Innovative and creative orthopaedic design and treatment modalities have often been the focus for articles and reports published on the pages of *Innovations*. As the editors prepared the current issue, we reflected on the continuing evolution of this journal and noted another major theme coming to the forefront – Validation. Improving patient outcomes and the user experience are long-standing founding principles for Exactech. We are often reminded that robust objective assessment is an important lens for viewing medical interventions and is essential for the surgeons and others who participate as partners in improving the care and results for a broad group of patients.

This edition of *Innovations* presents the collaborative work of an international group of authors in sharing their ideas and their reporting of objective measures of clinical outcomes enhanced by using advanced technologies. In addition, several surgical colleagues have shared their recent experiences in patient and practice management as well as improvements made in the O.R. in an ever-changing health care delivery environment.

We hope you find the articles informative and useful in your practice, and, as always, we look forward to your feedback.

CAOS TKA PROVIDES IMPROVED FUNCTIONAL OUTCOMES COMPARED TO CONVENTIONAL TKA

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INTRODUCTION

Computer-assisted orthopaedic surgery (CAOS) has been shown to offer a clear advantage regarding surgical accuracy in total knee arthroplasty (TKA) with a body of research studies demonstrating a significant reduction of alignment outliers compared to conventional TKA instrumentation.^{1,2} However, conflicted data exists in the literature for a consensus regarding the advantage of CAOS technology in clinical outcomes or satisfaction rates for the patient. While some studies have shown superior functional outcomes in CAOS TKA compared to its conventional counterparts,³ others reported no difference between CAOS and conventional cases.⁴ More studies are needed to further contribute knowledge and evidence on this topic. The objective of this study was to compare short-term clinical outcomes between TKA cases performed using a contemporary CAOS system and cases with conventional instrumentation.

MATERIALS AND METHODS

With approval from the institutional review board and signed informed consents from the patients, a prospective, multicenter, consecutive TKA case series was collected by three surgeons from three different clinical sites [2 US sites, 1 EU site] using the same implant system. Seven hundred and ninety-five (795) patients were enrolled with surgery dates between November 2009 and September 2018, including 334 CAOS TKA cases and 461 conventional TKA cases. Each surgeon performed both CAOS and conventional surgeries. Patient demographics, baseline clinical measurements, and the latest minimum one-year follow-up visit were reviewed and compared between the CAOS TKA group and the conventional TKA group. The clinical measurements investigated were Range of Motion (ROM), Knee Society Score (KSS: knee, function, pain, and each sub-component measure), and patient satisfaction Visual Analog Scale (VAS 1-10, with 10 indicating the highest satisfaction). All data analyses were performed using custom scripts in R 3.6.1 (RStudio, Inc., Boston, MA, USA). Two-sample t-tests were used for continuous outcomes, and the chi-squared test was used for binary outcomes. To further assess the detected post-operative significance, a multivariate regression analysis was performed to assess the impact of region (EU vs US) and treatment type (CAOS vs conventional). Statistical significance was defined as $p \leq 0.05$.

A	CAOS	Conventional	P
N			
Enrolled	334	461	-
Type+ Follow-up Available	215	350	-
Mean Follow-up Period (months)	20.7	38.1	-
Age (year)	67.5±9.2	63.9±9.5	<0.01
BMI (year)	30.7±7.1	12.1±6.4	<0.01
Male (%)	17.7%	44.7%	0.09
Primary OA (%)	89.2%	85.8%	0.22

B	CAOS	Conventional	P
Preop			
ROM	111.2±15.8	113.5±13.2	0.07
KSS Function	49.2±20.4	45.4±19.3	0.02
KSS Knee	44.9±16.7	45.2±16.3	0.70
KSS Pain	8.9±11.9	7.5±10.2	0.11
Postop			
ROM	121.7±12.3	117.5±12.2	<0.01
KSS Function	78.3±20.5	71.8±23.3	<0.01
KSS Knee	80.5±20.1	79.8±21.3	0.63
KSS Pain	40.4±13.2	42.1±12.6	0.12

Table 1. A) Details of demographics and characteristics of the study cohort.
B) Summary of pre- and post-operative outcomes.

RESULTS

At the time of study, 215 CAOS and 350 conventional patients were available for analysis of patient reported outcomes with mean post-operative follow-up periods of approximately two to three years (Table 1A). Patients from the CAOS group were older and had higher BMI than those from the conventional group (p values < 0.01, Table 1A). Preoperatively, for the baseline measures, although CAOS patients had higher KSS function scores than patients in the conventional group, no significant difference was found in each sub-component measure for KSS function (“Walking”, “Stairs”, and “Walking Aid”) (Figure 1). No other differences existed between the two groups’ patient characteristics and preoperative baseline.

Post-operatively, a significantly higher ROM was achieved in the CAOS group compared to the conventional group (p values < 0.01, Table 1B). Additionally, higher KSS function scores were found

in CAOS patients compared to the conventional group (p values < 0.01, Table 1B). Differences were also seen in the sub-component measures. Compared to the conventional patients, CAOS patients scored significantly better in all sub-component measures (p values ≤ 0.05, Figure 1). No difference was found in KSS knee and KSS pain scores. Although EU patients were associated with higher post-operative ROM, geographic region was not significantly correlated with KSS function and its sub-component measures. In contrast, CAOS surgery was significantly associated with better KSS function and sub-component measures (“Walking” and “Stairs”) compared to conventional surgery (p values < 0.04). Both groups achieved a mean satisfaction rate of 9 (N.S.). Fourteen (14) conventional cases were revised due to pain (5), loosening (3), infection (2), instability (1), and patellofemoral complications (3). Four (4) knees in the CAOS group were revised due to infection.

DISCUSSION

This study demonstrated significantly better short-term functional outcomes for the patients who received CAOS TKAs compared to those who received a conventional TKA. Aligned with the reports from previous studies,^{3,5} the findings from this study added to the existing evidence of the benefits of CAOS in achieving improved clinical outcomes compared to conventional TKA. Furthermore, the CAOS group demonstrated excellent short-term survivorship with zero (0) cases of early failure due to causes linked to post-operative mal alignment.

This study presented only short-term outcomes. Mid- to long-term performance of the CAOSTKA of this study cohort remains to be shown. The short-term results reported by this study provide early evidence that the use of CAOS technology may provide better function and greater ROM in TKAs. Further recruitment of global study sites will provide for a more robust patient cohort moving forward.

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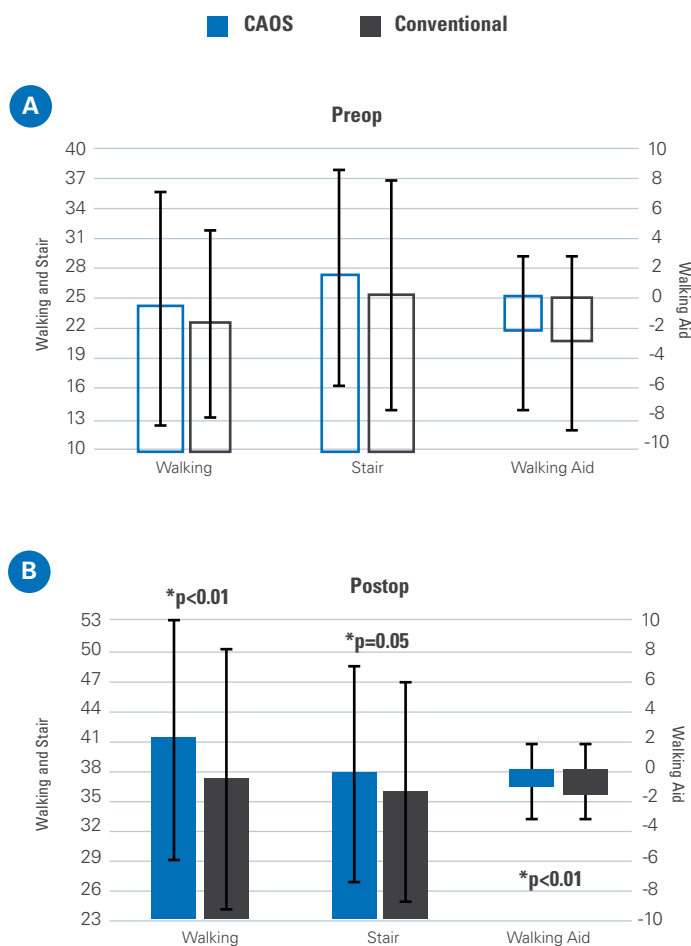


Figure 1. Comparisons between CAOS and conventional TKA groups regarding sub-component measures under A) preoperative and B) post-operative KSS function. Preoperatively, all sub-component measures were statistically equivalent between CAOS and conventional groups. In contrast, all sub-component measures demonstrated better outcomes in the CAOS group compared to the conventional group. Charts for KSS knee are not shown due to no difference in findings for the post-operative comparisons.

CAOS AUGMENTED MECHANICAL INSTRUMENTATION PROVIDES VERSATILITY AND IMPROVED ACCURACY DURING TOTAL KNEE ARTHROPLASTY

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INTRODUCTION

Accurate positioning of the knee prosthesis is critical for the success of total knee arthroplasty (TKA).¹ However, with mechanical (neutral) alignment surgical philosophy, only 70-80% of the conventional TKA cases can achieve satisfactory accuracy (within $\pm 3^\circ$ of varus/valgus relative to the mechanical axis).^{2,3} Furthermore, it still remains unsolved that up to 20% of patients are dissatisfied with their surgery.⁴ To improve the outcome of TKA, emphasis has been made that a surgeon should minimize surgical errors that lead to malalignment. Additionally, new surgical philosophies, such as natural alignment, have been applied as healthy knees demonstrates constitutional varus in up to 32% of adult men and 17% of adult women.⁵ This philosophy proposed that restoration of a slight varus alignment in varus knees during TKA may offer benefits to better post-operative natural kinematics.⁶ Yet, in actual practices, it is a paramount technical challenge to determine and achieve a natural alignment using conventional TKA instruments with sufficient efficiency and accuracy.

Computer-assisted Orthopedic Surgery (CAOS) offers increased accuracy and precision to the bony resections compared to the conventional techniques.⁷ This technology may offer a versatile tool to accommodate both mechanical and natural alignment surgical philosophies. However, one of the drawbacks for its adoption by the surgeons may be the inconvenience of switching from conventional instruments to CAOS-specific instruments. To remove the barrier to its adoption, a novel system has been introduced to augment conventional mechanical instruments with CAOS technology. In this study, the surgeon author sought to demonstrate and assess the impact of the CAOS augmentation on conventional instrumentation regarding resection accuracy and application of both surgical philosophies.

MATERIALS AND METHODS

With IRB oversight and its determination of exemption according to 45 CFR 46.104 category #4, a retrospective consecutive TKA case series conducted by the surgeon author was reviewed. The series consisted of 50 cases performed with mechanical instrumentation augmented by CAOS, matched with 101 conventional cases performed prior to the series using the same mechanical instruments. All the conventional cases targeted mechanical alignment due to the difficulty and low reliability of applying target natural alignment amount. In the CAOS augmented cases, natural alignment (2-3° residual varus) was targeted for preoperative alignment of more than 5° varus. As such, the acceptable range

Instrumentation	N	Age (yr)	BMI	HKA* (°)
Conventional	101	70.2 ± 9.2	30.5 ± 5.2	-1.1 ± 5.8
CAOS Augmented	50	67.3 ± 7.8	31.2 ± 4.6	4.5 ± 6.7
Preop Varus > 5°	27	66.7 ± 8.1	31.5 ± 4.6	9.6 ± 2.6
Other	23	67.9 ± 7.6	31.0 ± 4.6	-1.4 ± 4.9

* A positive value indicates varus alignment

Table 1. A summary of patient demographics and preoperative alignment in the CAOS augmented and conventional groups.

for the natural alignment cases was set to be 0°-5° (2-3° ± 3°), taking into account that in no cases the surgeon accepted more than 5° varus in the final alignment. The rest of the cases aimed for mechanical alignment.

Surgical time, speed of recovery, and alignment outcomes were collected, including tourniquet time, length of stay (LOS), and long-leg weight-bearing coronal alignment (hip-knee-ankle angle) measured at six-month post-operative. Outliers in alignment were identified as hip-knee-ankle angle within ± 3° regarding mechanical axis for the mechanically aligned cases, and within 0°-5° varus for the naturally aligned cases. The results were compared between the conventional and CAOS augmented groups. Statistical significance was defined as $p < 0.05$.

RESULTS

No significant difference was found in the patients' age and BMI between the CAOS augmented group and the conventional group (p values ≥ 0.40) (Table 1). Preoperatively, the CAOS augmented group was on average more varus than the conventional group (Table 1).

Among the 50 CAOS augmented cases, 27 were performed under natural alignment philosophy as they exhibited preoperative varus alignment of more than 5° (ranged from 6° to 15°). For both mechanically and naturally aligned groups, CAOS augmentation of the mechanical instrumentation did not increase tourniquet time from the conventional group ($p > 0.04$) (Figure 1A, B). The CAOS augmented patients had significantly shorter LOS (by 0.4 day) than the conventional patients (Figure 1C, $p = 0.02$). The use of CAOS augmentation exhibited significantly lower alignment outlier rate (2.4%) compared to the conventional cases (30.0%) ($p < 0.01$) (Figure 1D).

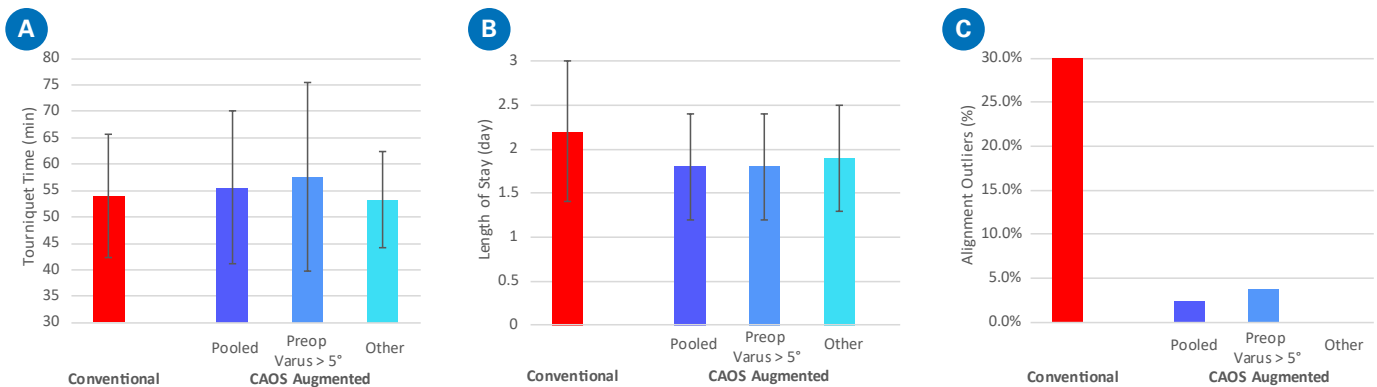


Figure 1. Comparison of A) tourniquet time, B) length of stay, and C) alignment outlier % between the conventional group and CAOS augmented group.

DISCUSSION

This study reported no increase in surgical time, shorter length of stay, and significantly reduced postoperative alignment outliers with the introduction of CAOS augmentation to conventional mechanical instrumentation during TKA. Furthermore, the technology enabled the application of natural alignment surgical philosophy in the varus knees. In contrast, conventional instruments do not provide a way to measure and set patient-specific alignment target. Even if the natural alignment target may be defined by specially designed conventional instrumentation, the inherent variability from the use of such instrumentation may be significant enough to impede a surgeon's ability to achieve a pre-defined natural alignment value. It has been shown that approximately 30% of the TKA cases using conventional instrumentation had alignment errors exceeding 3°.8,9

The CAOS augmentation greatly facilitated the surgical technique by offering the ability to quantify the alignment target, provide guidance to bony resection, and assess the accuracy of the achieved alignment.

In conclusion, the study demonstrated that augmenting conventional mechanical instrumentation with CAOS technology can be advantageous in achieving improved alignment accuracy, speed of recovery, and offer surgeons the versatility in applying preferred alignment surgical philosophy without the compromise of surgical time. Future follow-up of the patients' outcome may provide further assessment of the CAOS assisted naturally aligned TKA.

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TOTAL KNEE ARTHROPLASTY WITH CAOS AUGMENTATION

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INTRODUCTION

Computer-assisted Orthopedic Surgery (CAOS) offers increased accuracy to total knee arthroplasty (TKA) bony resections compared to the conventional techniques.¹ Despite the proven benefits, one of the drawbacks for the adoption of CAOS technology may be the inconvenience of switching from conventional instruments to CAOS-specific instruments. A recent technology added CAOS augmentation to conventional mechanical instruments, removing the need for significant instrument relearning. The system has been shown to have a minimal learning curve² and offers good usability and has been demonstrated to be non-disruptive to the surgical flow during its early adoption, reported by a subjective survey of users.³

As the clinical applications of this CAOS technology continue, further assessment is desired to confirm the promising results in a clinical setting. The purpose of this study was to collect and assess quantitative results regarding the use of the CAOS augmented technology* based on the combined experiences of a pilot surgeon group.

MATERIALS AND METHODS

A retrospective review was carried out on the technical records of 411 primary TKA cases (no patient information was reviewed). All cases were performed by a group of three surgeons using conventional mechanical instrumentation augmented by the CAOS technology. Three analyses were performed on the technical records regarding:

Efficiency of the CAOS augmented technology: The time spent on landmark acquisition and CAOS guidance, as well as the total CAOS-guided surgical time were assessed.

Usage and scope of intra-operative CAOS guidance: The location of the initially placed tibial and femoral cutting blocks were reviewed, from which the percentage of cases with the cutting block initially placed at greater than 2° varus/valgus was calculated. When there was a need to correct the initial placement of the cutting block, the surgeon turned an adjustment knob on the block with each turning “click” corresponding to a one-degree or -mm adjustment increment. The amount of adjustment in the coronal/sagittal alignments and resection depth were assessed.

A		C		
Femur	1.0 ± 1.0	Alignment (°)	0.0 ± 1.3	0.1 ± 1.1
CAOS Guided Cutting Block Adjustment (min)		Resection Depth (mm)	-0.2 ± 1.4	0.2 ± 1.3
Tibia	1.2 ± 1.5	Unsigned (Absolute) Error		
Femur	1.1 ± 1.5	Alignment (°)	1.0 ± 0.9	0.8 ± 0.7
Total Time for CAOS Surgery (min)	11.1 ± 4.4	Resection Depth (mm)	1.1 ± 1.0	1.0 ± 0.8
%cases within 20 min	97.0			
%cases within 30 min	99.1			

B				
N Adjustment "Clicks"	Per Knee	Tibia	Femur	P (Tibia vs Femur)
Coronal Alignment	3.3 ± 3.0	1.7 ± 2.4	1.7 ± 1.8	N.S.
Sagittal Alignment	3.6 ± 3.0	1.6 ± 1.8	2.1 ± 2.4	< 0.01
Resection Depth	3.5 ± 3.7	1.7 ± 2.3	1.8 ± 2.3	N.S.
All Parameters Combined	9.8 ± 4.2	4.5 ± 2.6	5.3 ± 3.4	< 0.01

Table 1. A) Efficiency, B) resection accuracy, and C) scope of CAOS-guided adjustments in the TKA cases performed with CAOS-augmented mechanical instrumentation.

Accuracy of the bony resection: The intra-operatively measured deviations between the surgeon's set resection goal and the achieved bony resection (coronal and sagittal alignments and resection depth) were calculated to investigate resection accuracy.

RESULTS

On average, it took one minute or less for the acquisition of the anatomic landmarks on the tibia and femur, respectively (Table 1A). Similar results were found in the time spent on CAOS guided tibial and femoral cutting block adjustments. The total CAOS guided surgical time was found to be 11.1 ± 4.4 minutes per case, with 97.0% and 99.1% of the cases required no more than 20 minutes and 30 minutes, respectively.

In 19.8% and 22.4% of the cases, the initial cutting block placements had more than 2° error in varus/valgus alignment, respectively for the tibia and femur. The percentage reduced drastically to ~1% after the surgeon adjusted the cutting block based on the CAOS guidance. The scope of adjustment for all 411 TKA cases was summarized in Table 1B. Generally, each knee required correction on both alignment and depth parameters. Results showed a similar amount of corrections across coronal alignment (3.3° ± 3.0°), sagittal alignment (3.6° ± 3.0°), and resection depth (3.5mm ± 3.7mm) (n.s.) of

the knee. When comparing bone types, the adjustment of orientation and position of the femoral cutting block required more corrections compared to the tibial cutting block. Further analysis revealed that more corrections were applied to adjust the sagittal alignment of the femoral cutting block compared to those required for the tibial cutting block. High resection accuracy was achieved for both tibial and femoral resections (Table 1C).

DISCUSSION

This study reported the prevalence of inaccuracy in the position of manually placed cutting blocks during conventional TKA surgeries. It was observed that 20% of the time, the surgeons placed the cutting block with more than 2° deviation from the ideal coronal alignment, potentially impacting clinical results.⁴ Adding CAOS augmentation to mechanical instrumentation was demonstrated to substantially improve resection accuracy. With CAOS guidance, considerable adjustments were easily achieved to correct the cutting blocks to the proper position. Significantly more adjustment was needed in femoral flexion/extension compared to tibial posterior slope. This might be caused by the inaccuracy of the intramedullary reamer placement used to establish flexion/extension alignment to the mechanical axis, especially with the prevalence of femoral sagittal bowing. The results also demonstrated minimal impact on

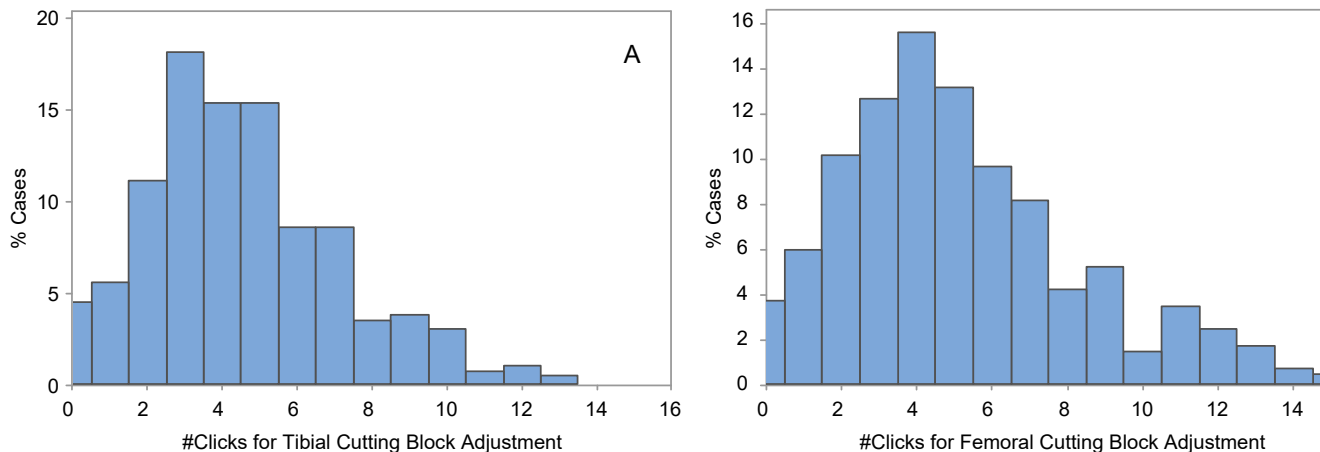


Figure 1. Percentage distribution of cases regarding the number of “clicks” (°/mm adjustment) required to correct the position of initially placed A) tibial and B) femoral cutting blocks.

the surgical efficiency (time) from incorporating the CAOS augmented technology into the surgical workflow.

While previous studies reported only 70% of conventional TKAs could achieve acceptable alignment accuracy,^{5,6} the findings from this study confirmed and emphasized the clinical need for mitigating error during manual conventional bony preparation, which can be addressed efficiently and accurately with CAOS-augmented mechanical instrumentation.

Computer-assisted Orthopedic Surgery (CAOS) offers increased accuracy to total knee arthroplasty (TKA) bony resections compared to the conventional techniques.¹

**The technology (ExactechGPS® TKA Plus) is a CT-free application designed to provide CAOS augmentation to conventional mechanical instrumentation. The system involves direct placement of the localizers onto the conventional femoral and tibial cutting guides. This system offers surgeons streamlined guidance for the proximal tibial and distal femoral cuts with minor change of instrumentation and surgical workflow.*

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MULTILEVEL MODELING OF RESECTION ACCURACY: INSIGHTS FROM 10,144 CLINICAL CASES USING A CONTEMPORARY COMPUTER-ASSISTED TOTAL KNEE ARTHROPLASTY SYSTEM

Abridged Version

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INTRODUCTION

As a successful treatment for advanced inflammatory and degenerative knee arthritis, total knee arthroplasty (TKA) is projected to expand by 600% to more than three million cases annually by 2030.¹ Associated with the exponential growth, an expected increase of revision TKA cases can be a substantial financial burden to both patients and society. Inaccurate surgical resections and the resultant malalignment are among the most common reasons for TKA failure.² These etiologies may also contribute to the phenomenon of 20% “unhappy” patients,^{3,4} as they have been shown to lead to worse functional and clinical outcomes compared to those of well-aligned knees.⁵⁻⁸

Numerous studies have confirmed the benefit of computer assisted orthopedic surgery (CAOS) in improving the accuracy of bony resection and limb alignment.^{9,10} However, there are some common shortcomings shared across the existing studies that often fall into the following categories: 1) the studies are not sufficiently powered to investigate geographic and inter-surgeon variance; 2) limited data is available on the “learning curve” to gain full benefit of a technology with a surgeon’s early adoption of the technology; 3) longitudinal performance of a specific CAOS system over time has been overlooked, despite constant updates in the software and hardware as a standard practice in most marketed systems; and 4) even though published meta-analyses offer global reviews of the CAOS technology, by nature, device differences and associated technical variations are excluded from the analyses, leading to significant differences in accuracy reported between CAOS systems.¹¹

It is unquestionably difficult to initiate clinical studies that encompass sufficient cases for the assessment of individual factors that may influence accuracy. Current cloud-based infrastructure now allows the archiving of technical data without the need to assess specific patient information, enabling comprehensive accuracy assessments based on a large number of cases performed by a given CAOS system. However, the large dataset is often accumulated at multiple levels (hierarchically structured), posing a unique challenge for analysis as it may violate the assumptions of common analytic methods such as linear

Grouping Variables	Definition of Categories	Number of Categories
Geographic Regions	APAC: Japan, Australia, Korea, Singapore, India EU: France, Switzerland, United Kingdom, Italy, Spain	3
Individual Established Surgeons	A data subset containing surgeons with $\geq 50^*$ cases experience with the CAOS system. Each individual surgeon was treated as one category.	41
Adoption Phases	Learning: combined cases #1-15 from all established surgeons Proficient: combined cases #36-50 from all established surgeons	2
Preop Alignment	Sever varus: $\geq 10^\circ$ varus Moderate varus: $3^\circ - 10^\circ$ varus Neutral: 3° valgus Moderate valgus: $3^\circ - 10^\circ$ valgus Severe valgus: $\geq 10^\circ$ valgus	5
Software Application	Software versions	6

**The selection of \geq cases to define established surgeons was based on consideration of maintaining sufficient sample size per category.*

Table 1. Grouping variables for the assessment of variability.

regression. Multilevel modeling offers several advantages to address the challenge,¹² including: 1) no requirement of independence for individual observations; and 2) effects of both individual and specific groups can be analyzed against the outcome of interest comprehensively and concurrently. This methodology has been applied to assess healthcare data variations in multiple categories, such as geographic region, socioeconomic status, and different attributes in care networks based on large datasets.¹³⁻¹⁵

By integrating the above described concepts of CAOS system specific accuracy performance, consideration of multiple factors that may impact accuracy, and methods for analyzing hierarchical data, this study aimed to apply multilevel modeling to assess resection accuracy across the entire TKA application history of a modern CAOS system. Specifically, the authors sought to determine the impact on accuracy from 1) geographic region; 2) inter-surgeon difference; 3) surgeon's adoption of the technology (learning

vs proficiency); 4) preoperative mechanical alignment status; and 5) historical progression of the CAOS application (software versions).

A retrospective review was conducted based on a proprietary cloud-based web that archives all TKAs performed using a modern imageless CAOS system (ExactechGPS®, Blue-Ortho, Gieres, FR). All completed cases are stored as deidentified reports that contain only technical information on the surgery (no patient information of any sort). Similarly, all surgeons are de-identified with only their geographic information (country of practice) available. A set of grouping categories were identified as variables that might affect alignment accuracy, including geographic regions, inter-user differences across established surgeons (surgeons with at least 50 cases experience with the CAOS system), adoption phases, preoperative mechanical alignment status, and versions of the CAOS software application (Table 1).

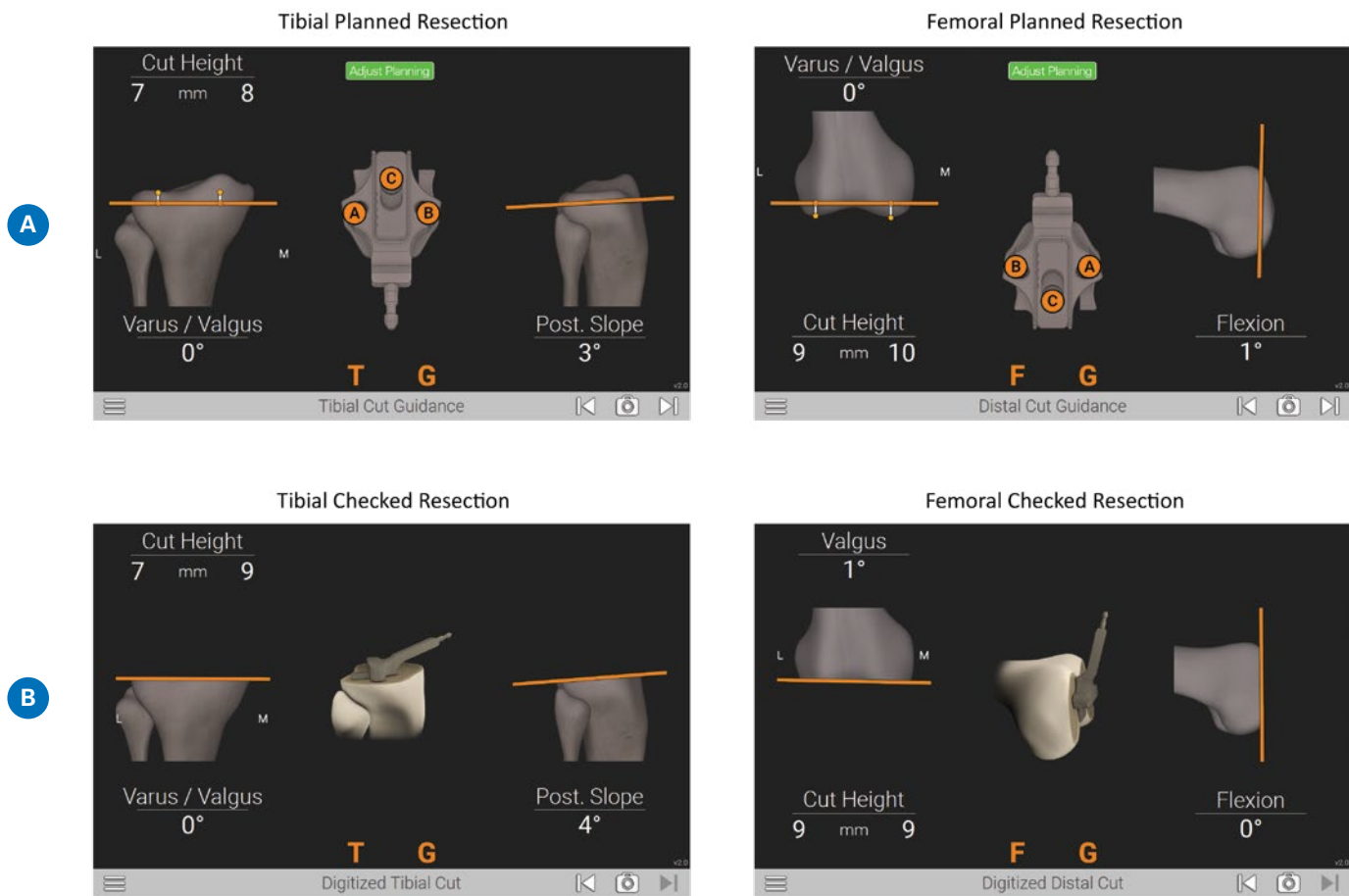


Figure 1. A) Alignment target was planned before bony resection, and B) digitized after bony resection using an instrumented checker. Resection error in alignment was calculated as the deviation from the planned resection to the checked resection.

The following surgical parameters were extracted (Figure 1): 1) planned resection: the resection parameters determined by the surgeon prior to the bony resection. These parameters reflected the surgeon's resection targets for the CAOS guidance; 2) checked resection: digitalization of the actual bony resection surfaces, acquired based on the actual bony resection using an instrumented checker.

Resection errors (accuracy) were assessed between the planned and actual resections in the coronal plane referencing the mechanical axis, for both the tibia and femur. A resection was considered acceptable if there was no more than 2° of error. Unconditional multilevel modeling was applied to understand whether and where the variability was located in the resection errors in both tibia and femur with regard to the grouping categories. For each model, level-1 and level-2 variances, as well as the intraclass correlation (ICC) were computed.

Specifically, the following questions were explored:

1. Does significant variability exist in resection errors in any grouping category(-ies)?
2. If variability is found to exist in a grouping category, is it clinically meaningful?

The first question was answered by the identification of any significance ($p < 0.05$) from a z test on the variance estimate of the level-2 variability related to a specific grouping category. In order to answer the second question, an intraclass correlation coefficient (ICC) value greater than the common variability from observational type studies (reported as $ICC = 0.15 - 0.2516$) indicated the existence of meaningful variability in alignment accuracy for the associated grouping category.

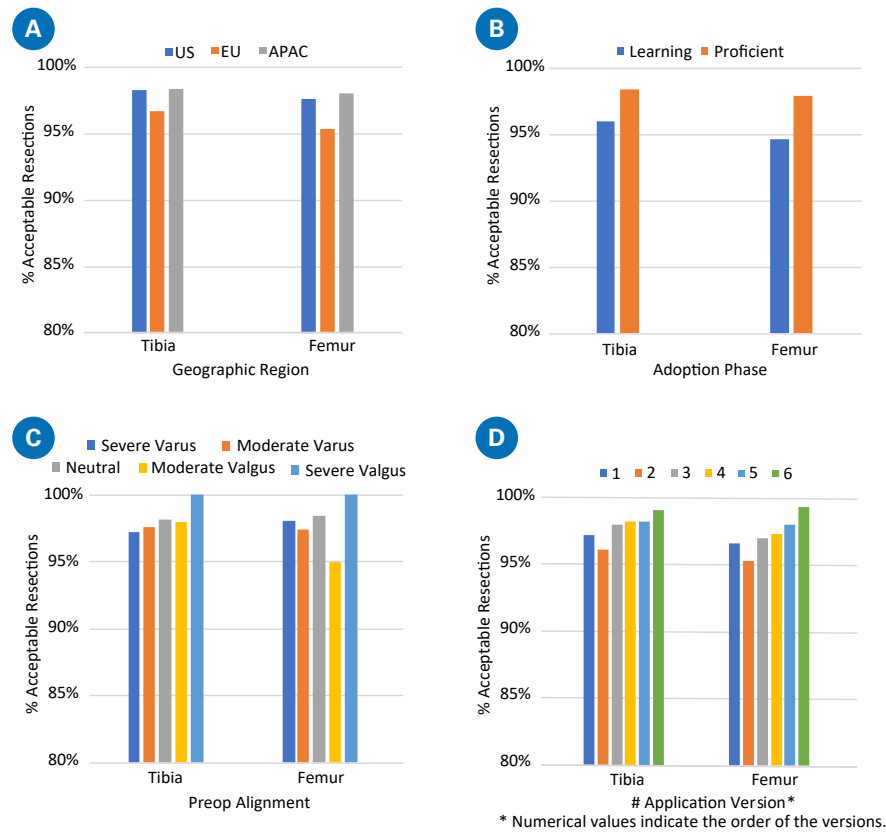


Figure 3. Percentage of acceptable resections (<2° alignment error) across grouping categories of geographic region, adoption phase, preoperative alignment, and application version.

Level II Grouping Variables	Variance Estimate	Standard Error	Z-value	P-value	ICC
<i>Tibial Alignment Error</i>					
Geographic Regions	0.0000	--	--	--	0.0000
Individual Established Surgeon	0.0453	0.0111	4.0900	<0.0001	0.0736
Adoption Phase	0.0000	--	--	--	
Preop Alignment	0.0019	0.0021	0.9000	0.1842	0.0027
Application Version	0.0029	0.0023	1.2500	0.1048	0.0038
<i>Femoral Alignment Error</i>					
Geographic Regions	0.0014	0.0016	0.8600	0.1952	0.0016
Individual Established Surgeon	0.0161	0.0053	3.0500	0.0011	0.0223
Adoption Phase	0.0001	0.0023	0.0400	0.4847	0.0001
Preop Alignment	0.0000	--	--	--	0.0000
Application Version	0.0003	0.0006	0.4500	0.3248	0.0003

Table 2. Variance estimates and ICC values for level II variables from multilevel models. Note that extremely low (0.0000) variance estimates were found across categories in some group variables (meaningful standard error not observed). The associated z-value and p-value were not calculated as the data did not support a hypothesis test (z-test).

beam. Although three-dimensional computer tomography (CT) analysis is suggested for a more accurate alignment measurement,¹⁹ a universal CT evaluation for all patients in this study was impractical. The choice of intraoperative instrumented measurement provided a consistent and accurate 3-D method for assessing resection alignment accuracy.

In conclusion, this study applied an advanced statistical tool to provide a comprehensive, clinically relevant evaluation of a modern CAOS system for total knee arthroplasty. The analysis considered potential impact from an extensive list of factors for a thorough understanding of resection errors based on a large data set collected through the application history of the system. The analysis outcomes demonstrated that the studied modern CAOS system offers an accurate and precise solution to help the surgeon achieve their surgical resection goal.

*The full version of this article can be found in Volume 27, Issue 3 of The Knee.

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THE POWER OF DATA COLLECTION

American astrophysicist Dr. Neil deGrasse Tyson once said, “Any time scientists disagree, it’s because we have insufficient data. Then we can agree on what data to get; we get the data; and the data solves the problem. Either I’m right, you’re right or we’re both wrong.” In orthopaedics, *data is king*.

Since the inception of the Equinox[®] Shoulder System in 2004, Exactech and its surgeon partners have made the science of data collection part of their mission. With 35 collection sites across the United States and Europe, the Equinox database includes information on demographics, comorbidities, implant specifics, 7 PROMs, ROM, radiographic data, and complications—all using standardized forms—for more than 10,000 shoulder cases. This multi-center collection using standardized forms creates the volume of evidence needed to produce the necessary statistical power for accurate analysis of the data; otherwise, the data would not be generalizable to a large patient population or to surgeons in different countries.

Some implant manufacturers and their consultants take non-standardized or under-powered data, such as individual user experience or small groups of surgeons’ outcomes, and present it as generalizable evidence. This makes it difficult for surgeons to know what they can and can’t trust. Accurate analysis of robust data is what surgeons need to make informed decisions about which implant to use and what surgical techniques to employ to do what is best for the patient.

The *Journal of Bone & Joint Surgery* recently published an article titled “Acromial and Scapular Fractures After Reverse Total Shoulder Arthroplasty with a Medialized Glenoid and Lateralized Humeral Implant: An Analysis of Outcomes and Risk Factors” by Routman et al. In this study, 4,125 shoulders from 3,995 patients were treated for primary reverse total shoulder arthroplasty using only one design of a reverse shoulder prosthesis¹—the Equinox rTSA System, a medialized glenoid and lateralized humeral implant. The Equinox reverse acromial and scapular fracture rate is 1.48 percent, which is more than two times lower than the prosthesis designs, whether inlay or onlay, referenced in the literature.²⁻⁵

Despite the comprehensive and extensive data, surgeons continue to disagree on whether implant design is associated with acromial and scapular fractures. One possible reason is that previous studies tend to lack the necessary statistical power for accurate data analysis to make the resulting claims and surgeons must depend on comparisons drawn from meta-analyses to try to answer this important question.

With the ever-increasing number of medical journals and online outlets available for publication, there should be an increased amount of scrutiny placed on editorial submissions that are accepted—and the underlying data within them—but that does not always seem to be the case.

Creating products for patients that solve clinical challenges requires dedication and investment. Over the last 17 years, Exactech surgeon collaborators and their research staffs have invested countless hours alongside Exactech’s multi-million-dollar investment to ensure that the Equinox Shoulder System is the most studied and published shoulder arthroplasty system on the market. The original medial glenoid lateral humerus design has not changed since its introduction—a feat that is truly unique within the industry. With over 430 literature references since 2004 and 27 peer-reviewed papers in 2020 alone, the Equinox database is a benchmark for new product development. It has also paved the way for continued use of the Equinox Shoulder System in Europe under the new EU Medical Device Regulations and enabled the use of machine learning to create predictive modeling applications and shoulder scoring systems, which will change and challenge the current way we approach shoulder surgery. The continuum of care is expanding, and data will support this growth. This is the power of the Equinox database.

Without clean, generalizable, sufficiently powered data, the conversation will continue to be “I’m right, you’re right or we’re both wrong”; and while this provides a platform for heated debate within the orthopaedic community and for capitalism, to prosper, the question of what is right for the patient will continue to be our guide.

Thoughts contributed by Jessica DeGrasse, Exactech, Inc.

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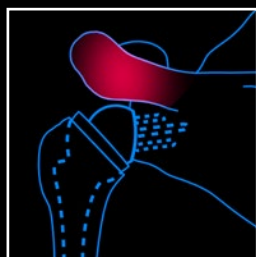
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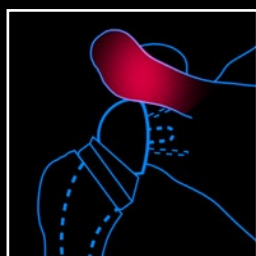
Not All Reverses Are Created Equal

Equinox[®]: >2x reduction in acromial and scapular fracture rate

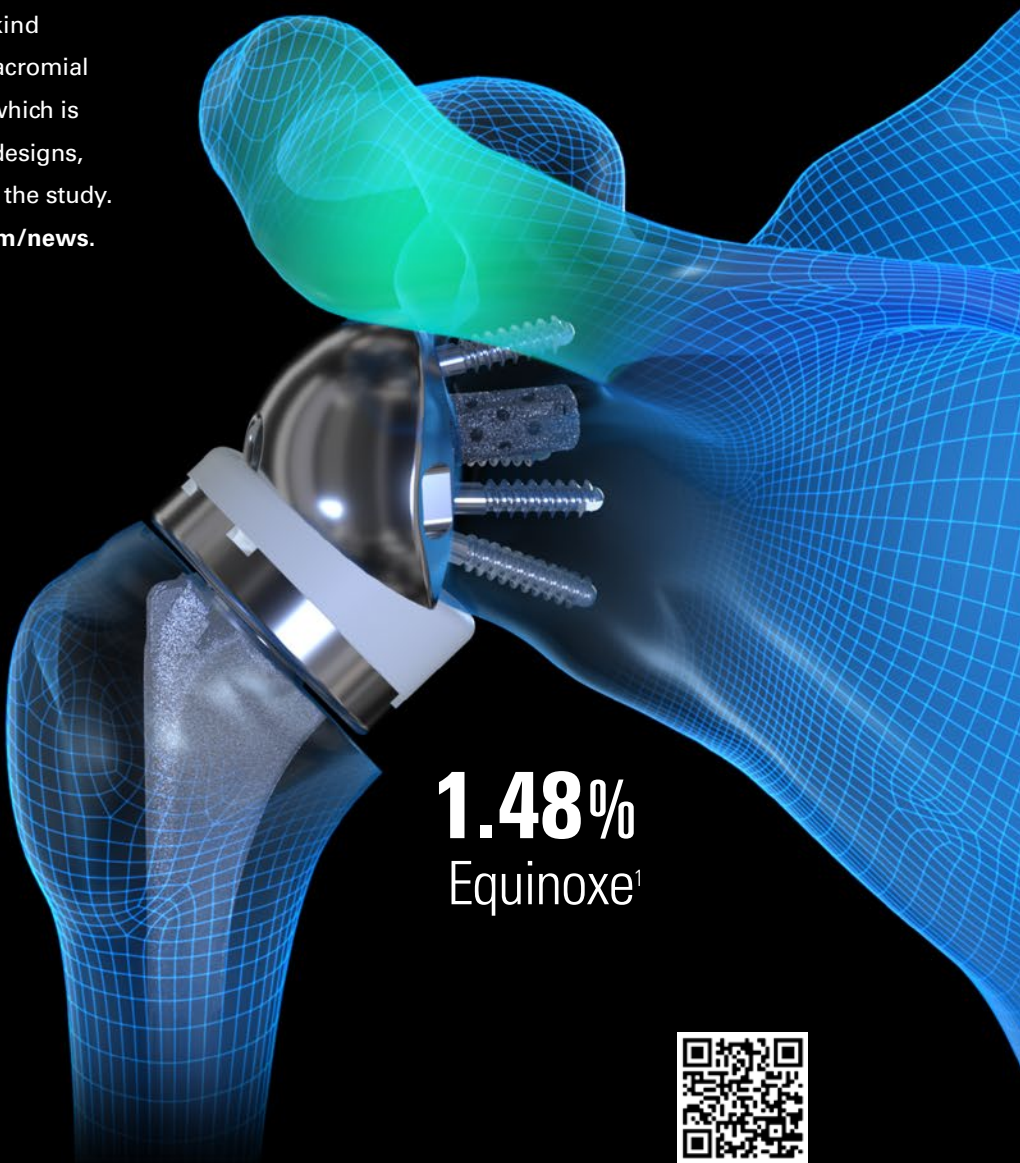
The largest published study¹ of its kind demonstrates the Equinox reverse acromial and scapular fracture rate is 1.48%, which is >2x lower than the other prosthesis designs, whether inlay or onlay, referenced in the study. Learn more at jbjs.org¹ and exac.com/news.



3.1-10.2%
Lateral Glenoid Inlay^{2,3}



4.3%
Curved Stem Onlay⁴



1.48%
Equinox¹



Scan to learn why biomechanics matter.

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THE IMPACT OF PREOPERATIVE PATIENT EDUCATION ON CLINICAL OUTCOMES

Clinical Contributor



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SCOS Orthopedic Specialists
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INTRODUCTION

A 2017 study published in the Current Reviews on Musculoskeletal Medicine stated that patient education prior to joint replacement surgery has been shown to decrease anxiety, improve post-operative pain control, provide more realistic expectations of surgery, and increase the patient's understanding of their surgery. As a result, the incorporation of preoperative education programs for elective joint replacement can lead to lower hospital length of stay, higher home discharge, lower readmission, and improved cost.¹

In this article, Ari Youderian, MD shares his personal experience with preoperative patient education and provides valuable insights for fellow orthopaedic surgeons to expand their pre-op protocols and incorporate patient discussions of advanced technology.

Talk us through your preoperative protocols and your expectations of patients prior to surgery?

We must recognize that all patients are different in their expectations, knowledge, background, and education. To that end, I have created a multi-modal approach to my patients' preoperative education, with a lot of reinforcing repetition.

My patients initially meet with me to discuss their condition, previous treatments, medical history, and candidacy for shoulder replacement. We review their initial imaging studies as well as the overall treatment process from preoperative to full recovery six to 12 months later. I also present an initial recommendation for either *outpatient or inpatient* surgery, based on their health status.

All patients attend a preoperative visit guided by my physician assistant. They review the process, day of surgery details, wound care, obtain DME, and sign paperwork. I then answer any remaining questions and obtain informed consent. We also provide and review a set of initial post-operative exercises.

Inpatient surgical patients are recommended to attend a shoulder-specific joint class provided by the hospital's joint surgery coordinators. We have tailored and simplified the program (which I helped develop) for my shoulder patients with specific protocols and expectations. Approximately 90 percent of my patients attend these classes.

Outpatient surgical patients are linked with a nurse navigator who provides preoperative shoulder replacement education, preoperative testing, day of surgery details, and outpatient return-to-home planning. The navigator follows up with the patients after surgery via phone calls. All outpatient patients are required to participate.

My expectations for my patients are centered on understanding what their disease is and the procedure that I am planning to perform. After surgical decision making and planning is complete, the expectations shift toward preparation for surgery and, most importantly, after surgery. Setting the goals for length of stay, typically 0-1 night, is critical. Patients must understand their rehabilitation plans, post-operative medications, and prepare for any post-operative restrictions. The ultimate goal is to have them comfortable when they return home to alleviate any anxiety and eliminate any surprises.

What do you think the impact of preoperative education has been on your overall clinical outcomes?

Clinical outcomes are a combination of both patient satisfaction and physical assessment. I believe that in both of these categories preoperative education is a winner.

We know that early range of motion after shoulder replacement is most important for a successful outcome. The patients learn early on that exercises starting on post-operative day one are expected. These are taught and reviewed by my physician assistant as well as reviewed at the preoperative education class. Handouts are provided in both instances, and patients are ready to perform these from the start.

The patient satisfaction outcome scores are typically based on patient perception of post-operative pain and function. When the process is clear, the people they meet are helpful and informative, and their expectations are met or exceeded; their outcomes are mostly positive. I am confident that as the preoperative expectations are set early on and repeated often, they drive higher patient satisfaction scores.

We have minimized the hospital length of stay to under one day, as well as lessened the need for post-operative home health requirements. My findings are anecdotal at this point but in addition to these truths, we see less patients calling after surgery with questions.

Do you have any tips for explaining complex surgeries or advanced technologies to your patients in a way that's easy to understand?

Tip #1 Keep it Simple

Promoting advanced technology doesn't mean explaining the gritty details (unless the patient wants or asks for them). It does mean getting the points across but with simple language. For example, when I explain to patients that I like to use the ExactechGPS® shoulder preoperative planning application, I don't say, "I am planning to use a software optimization program that incorporates your DICOM images from a computed tomography scan." I typically say, "I plan your surgery to be more accurate² with a computer program that lets me see your bone in 3D and figure out what size implants would be best for your shoulder."

Tip #2 Keep an Open Dialogue

Some patients can follow what you are saying and like the details and some would rather not know them all. Ask your patients throughout the process about their level of understanding and if they are satisfied with the information that you have provided during their visit. Remember - Long, one-way lectures are rarely well-absorbed.

Tip #3 Use Visual Aids

Some patients may learn better with visual aids such as joint models, images or videos. I often use models and even compare them to the patient's 3D reconstructions while explaining shoulder replacement. There are many aids that can be used, and I often refer them to my own website and the company website for more detailed videos and procedural guides.

What advice would you give to a new orthopaedic surgeons on first developing preoperative education plans?

Tip #1

Don't try to reinvent the wheel. Most hospitals and surgery centers have developed some of these processes already. You can easily implement some of your own ideas and practices as well as guidelines from your training programs into these programs. New surgeons do not have to do this

alone. Partnership with a hospital or surgery center can help provide the resources you need. They typically want the business and will make efforts to provide services for your patients, including joint classes and materials.

Tip #2

Spend the extra time yourself with your patient. Especially in the beginning of your practice, your patients will trust you and appreciate the extra time and effort that they might not get from other, busier surgeons. You can tailor your education efforts to be more efficient as you yourself become busier.

Tip #3

Gather appropriate brochures, handouts, or leverage corporate vendors to help provide materials for your patients to reiterate and expand upon the information you provide.

Tip #4

Continue to connect with your patients after surgery to gain feedback on the entire process. This way you can adjust your education programs or processes to maximize your patient satisfaction and clinical outcomes.

Interview conducted by Allison Downey, APR, CPRC, Exactech, Inc.

DISCLAIMER: The opinions expressed in this article are that of one surgeon. Individual results vary. With any surgery, there are potential risks and recovery times may differ depending on the patient. Exactech, as the manufacturer, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience.

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CREATING EFFICIENCY IN THE O.R. WITH STREAMLINED INSTRUMENT SETS

The number of total joint replacements is growing rapidly, and the current trend suggests that the number of total joints performed will double by 2030.¹ As the population ages in the United States, and the older generations graduate to more advanced stages of arthritis, the need for joint arthroplasty surgery will expand. In addition, the transition to outpatient total joint arthroplasties over the past five years has caused a shift toward shortened hospital stays and increased outpatient procedures. In 2017, only 15 percent of joint replacements were performed in the outpatient setting, and current estimates suggest that by 2026 that number will be closer to 50 percent.²

Clinical Contributor

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Considering these statistics, we answered the following questions regarding the implementation of the Exactech ExacSETS[®] into our hospital and ambulatory surgery settings and cannot overstate the opportunities it afforded.

How did the O.R. experience change from the standard setup to the two-tray setup?

I operate in two different settings—an Ambulatory Surgery Center (ASC) and traditional hospital surgical suites. In the hospital setting, the rooms are typically larger and more spacious. While it is an advantage to conserve space in any setting, there is a difference in space saving in a hospital versus an ASC. Orthopedic surgery requires a great deal of instrumentation, and the room configurations are oftentimes more complicated and more cluttered than other service lines. With that in mind, most hospitals accommodate orthopedic services with larger rooms. However, in an ASC setting, room size and maneuverability are usually confined. While an extra table or mayo stand in a hospital O.R. may not affect the space allocation, it would absolutely affect the available space in an ASC setting.

With the two-tray ExacSETS, we have been able to go from two large back tables to one large back table (Figures 1 and 2). When accounting for surgical side space, in addition to the scrub tech and fellow, this modification makes a small O.R. feel much larger.



Figure 1. One table room set-up using ExacSETS.



Figure 2. View of one table set-up using an ExacSETS tray.

Practical Efficiency

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Compact and mobile



Time neutral¹

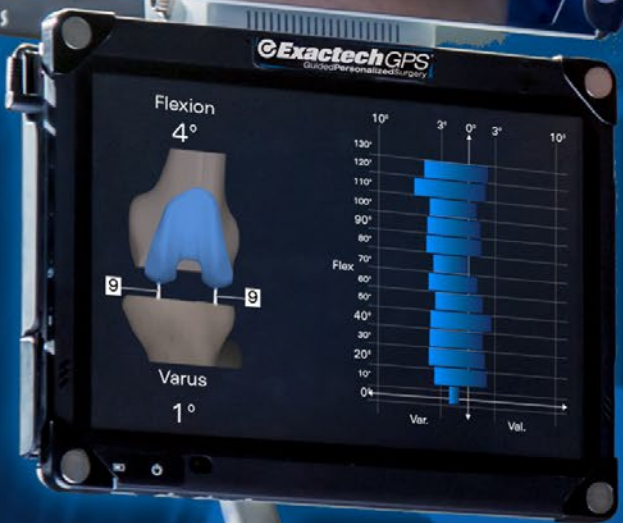


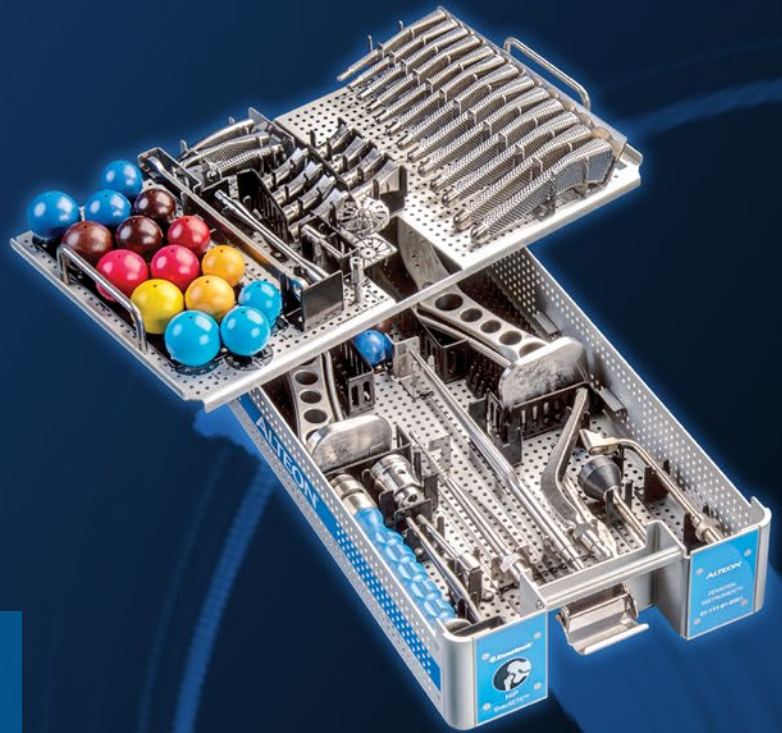
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Personalized to your surgical technique

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Efficient Instrumentation

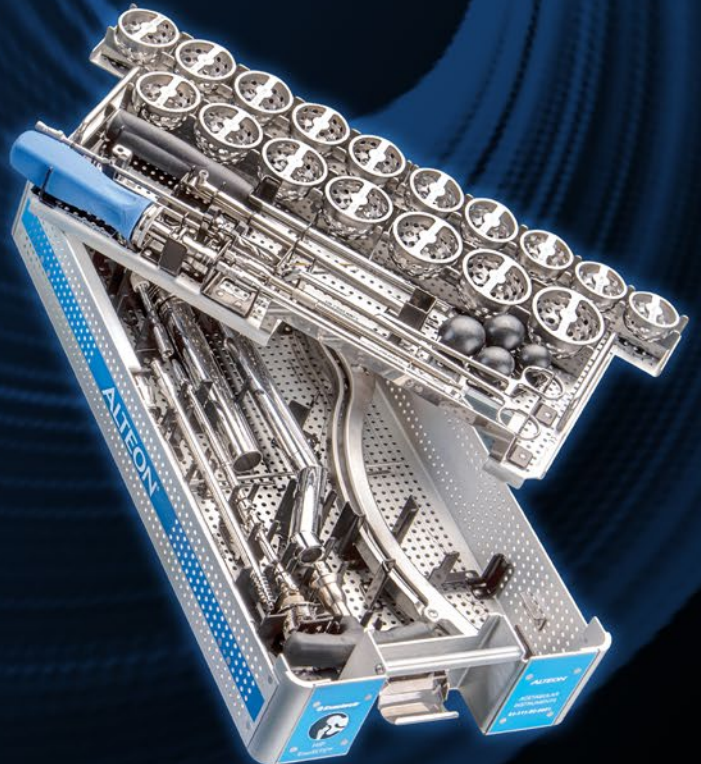
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Figure 3. Six-tray instrument system.

Did you feel that you had to compromise anything from your standard surgical flow?

Actually, we felt the exact opposite. The flow seemed to be more efficient, and the time from room breakdown to opening felt much easier. Some systems require four to six pans to be opened for each case (Figure 3). With the switch to the ExacSETS, the room staff almost immediately noticed a difference. While it might not seem like a big difference to the surgeon waiting in the lounge for the room to be opened, our ASC staff was ecstatic to open only two pans for each case (Figure 4). When we transferred the ExacSETS to the hospital setting, the staff took notice as well.

Needless to say, the number of trays opened can make a vast difference in the room morale and workload to the staff. Our scrub techs and room nurses were excited about the decrease in trays being opened. I didn't appreciate the numbers until one of my scrub techs noted that on a five-case day, we drastically cut the opening time down possibly because of a decrease in about 10 to 20 pans. Over the course of a day, those increments of time add up.

Was there a learning curve for you or your O.R. staff?

Honestly, not really. The pans are stacked a bit differently than the standard tray sets, but we quickly figured out that the instruments we needed were all available. The reamer sizes for a total hip range from 44mm to a 60mm. Head sizes range from 28mm to 40mm, with all plus and minus



Figure 4. Two-tray ExacSETS kit.

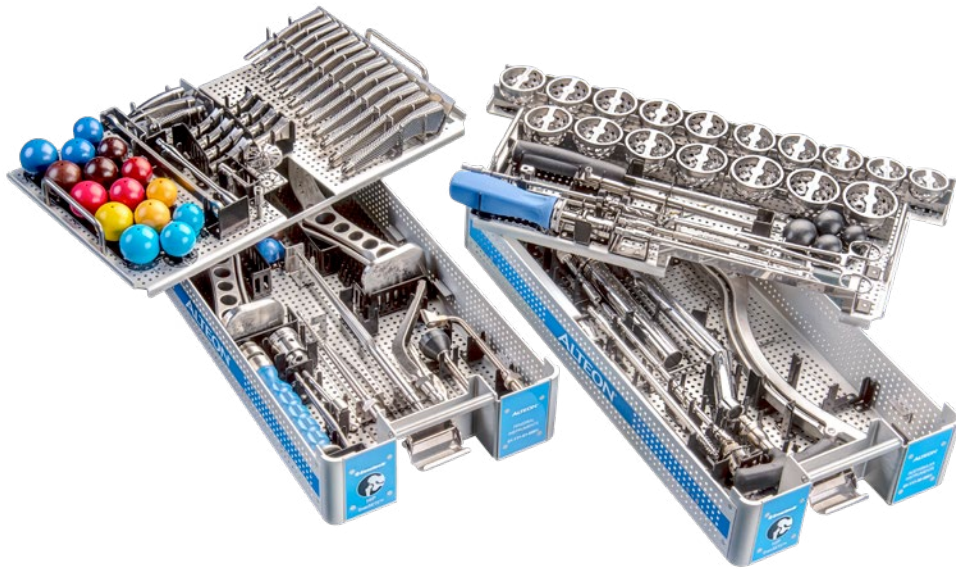
sizes available. In addition, all stem sizes in each grouping are available in standard and extended options. It's a wonder we haven't done this sooner.

Did you notice a difference in your Sterile Processing Department (SPD)?

Our SPD may have noticed the biggest difference. In addition to processing total joint tray sets, they also prepare and arrange other service lines. The task can be daunting, and the amount of work is demanding. Making sure the instruments are scrubbed, washed, and cleaned takes an enormous amount of time and effort. And that doesn't include sterilization time. It was immediately obvious that our SPD staff preferred the two pan ExacSETS. The difference between preparing a two-tray system versus a four- to six-tray system is significant not only for the day of surgery, but also when preparing for the next day's cases.

Overall, what did you experience as the benefits of using ExacSETS for your practice?

As an owner in an ASC, the cost savings is the biggest difference when comparing ExacSETS to the competition. The cost of preparing a tray of instruments includes scrubbing, washing, and sterilizing. That doesn't include the overhead associated with the upkeep for sterile processors, employee salaries and benefits, and the cost of chemical supplies. It has been estimated that the cost to sterilize one pan can be anywhere from \$125 to \$200 per tray. If we take the median of the expected cost at \$150 per tray,



used for 200 joints per year, the average cost savings would be \$60,000 a year for a two-tray system versus a four-tray system for a total hip. When comparing the same savings for a six-tray total knee system, the savings are \$120,000 per year. Those are real numbers that can significantly reduce the overhead of running an ACS.

In the future, I believe that one of the largest responsibilities for surgeons will be cost containment. Reducing overhead costs and increasing O.R. efficiency could be accomplished using the ExacSETS for total hip and knee arthroplasties.

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THE EVOLUTION OF INTERSPACE® KNEE: A CASE REVIEW OF THE NEW INTERSPACE KNEE AUGMENTED TIBIAL STEM (ATS)

Clinical Contributor

 **Timothy van de Leur, MD**

The Orthopaedic Institute
Ocala, FL



The InterSpace Knee has been a solution for surgeons for more than 20 years, and its extensive clinical data demonstrates its utility and effectiveness.¹ Since its inception, the number of revisions has risen, and with that comes more infected cases. The complexities that come with managing infected revisions can be unpredictable, especially after multiple revisions. With this in mind, it is important for surgeons to have options when they tackle these difficult cases where patients present different anatomies and varying levels of bone deficiencies.

“Infection is a difficult problem to treat and work through with patients. Oftentimes, patients don’t understand the challenges and just want a normalcy that includes a reduction in pain, a return to mobility, and elimination of the infection. The InterSpace Knee system offers straightforward sizing and trialing in the O.R., and to me, it has proven to be a simple and effective tool that has helped me help my patients return to some normalcy.”

“Over the last decade, I routinely formed and molded a stem to the distal portion of the InterSpace tibia and overcame the challenge of large defects with significant bone loss by adding more cement. Naturally, I am pleased with the new InterSpace Knee ATS and the option it gives me to add a stem, which makes up for larger bone deficiencies. The simplicity of the InterSpace Knee construct remains intact with the addition of the ATS as the intraoperative implant sizing options are easy to determine with the same trialing approach. I believe that adopting the ATS in infected revision cases is the next logical step to address a broader range of patients facing challenging deformities in the infection process.”

CASE REVIEW:

- 67-year-old male with chief complaint of left knee pain. Severe arthritis with bone-on-bone arthritis, cystic changes, bone spurs, and osteophytes was observed. TKA was performed.
- Two-month post-operative incision was clean, dry, and intact. Range of motion (ROM) was 5-125 degrees and films were normal. Patient was scheduled for 10-month follow-up visit.
- Patient was seen in clinic four months post-operative with complaints of lower back pain and pain on operative knee. Patient had resumed golfing daily. Patient received epidural injections from Pain Management for back pain.
- Patient returns five months post-operative with swelling and heat in operative knee; no drainage. Patient stated knee pain was not present prior to epidural injections administered two months prior for back pain. ROM was 0-120. ESR, CRP, and joint aspirate ordered for Synovasure study.
- After one week, patient reported back with hot, red, tender, ecchymosis with preserved ROM in the knee. ESR and CRP were elevated, Synovasure showed positive alpha defensin and neutrophil elastase, and culture positive for Staph. lugdunensis. Antibiogram showed sensitivities to ciprofloxacin, clindamycin, erythromycin, lefocloxacillin, rifampin, tetracycline, and vancomycin.
- Patient was taken to surgery for incision and drainage (I&D) and placement of antibiotic spacer (InterSpace Knee with Augmented Tibial Stem (ATS). Antibiotic beads left in the wound before closure.
- Two-week follow-up from spacer implantation, the patient expressed a reduction in pain as a 7/10. The wound was clean, dry, and intact, and sutures were removed.
- Films showed a well-fixed spacer, and patient demonstrated ROM of 0-90 degrees.
- At latest follow-up, the patient was instructed to be diligent in continuing antibiotics and following up with Infectious Disease (ID). There were no obvious signs of infection, and patient appears to be on path for reimplantation.

REFERENCES

1. Data on file at Exactech, Inc.

PREOPERATIVE IMAGES:



Lateral View, 5 Degrees

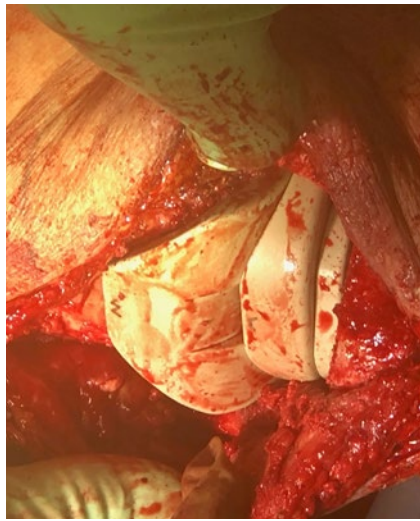


Standing

INTRA-OPERATIVE SIZING OF INTERSPACE KNEE WITH ATS:



Tibial Trialing with Femoral Measurement



Full Construct Trialing

POST-OPERATIVE FILMS OF INTERSPACE KNEE WITH ATS:



Standing AP View



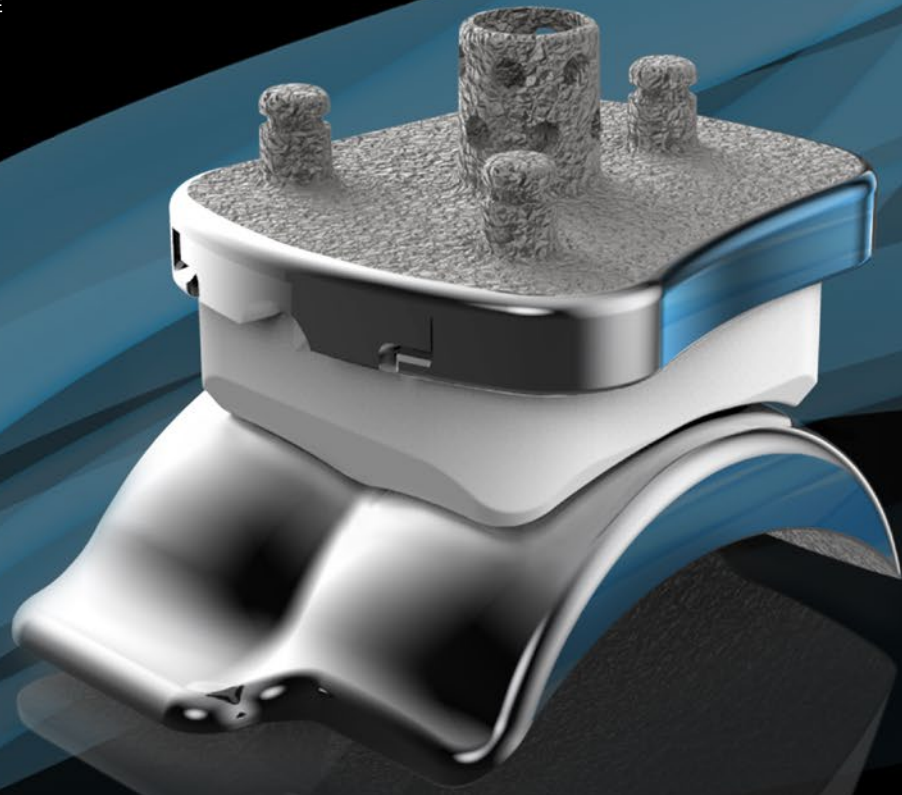
Lateral View, 5 Degrees

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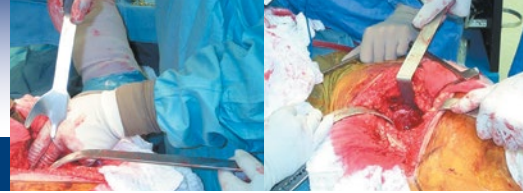
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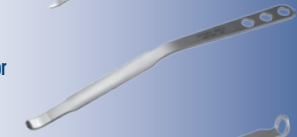
Extra Deep Modified Hohmann Retractor

PRODUCT NO:
4535-01



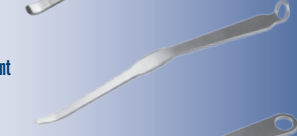
Extra Deep Long Narrow Blunt Hohmann Retractor

PRODUCT NO:
4540-01



Extra Deep Modified Blunt Hohmann Retractor

PRODUCT NO:
4550-01



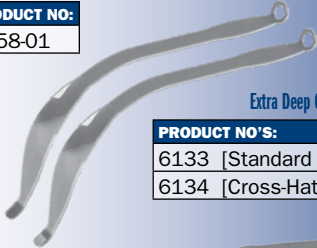
Extra Deep Hohmann Retractor

PRODUCT NO:
4558-01



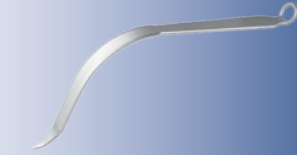
Extra Deep Cobra Retractors

PRODUCT NO'S:
6133 [Standard Tip]
6134 [Cross-Hatched Tip]



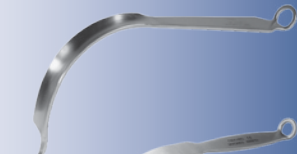
Extra Deep Single Prong Soft Tissue Retractor

PRODUCT NO:
6450-01



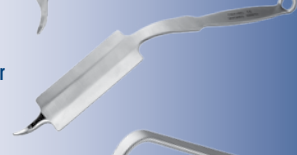
Extra Deep Single Prong Acetabular Retractor

PRODUCT NO:
6570-01



Extra Deep Modified Wide Hohmann Retractor

PRODUCT NO:
6595-01



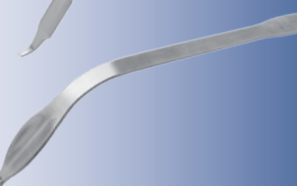
Extra Deep Bent Hohmann Retractor

PRODUCT NO:
7115-03



Extra Deep Large Cobra Retractor

PRODUCT NO:
7630-03



Extra Deep Mueller-type Femoral Neck Elevator modified by Tom Eickmann, MD



Extra Leverage Proximal Femoral Elevator

PRODUCT NO:
7640

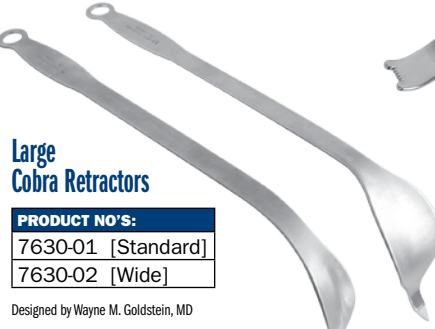
Designed by Wayne M. Goldstein, MD



Large Cobra Retractors

PRODUCT NO'S:
7630-01 [Standard]
7630-02 [Wide]

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Infero-posterior Acetabular Capsule Retractors

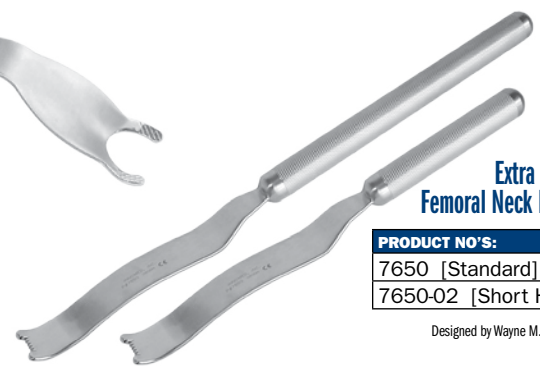
PRODUCT NO'S:
7620-01 [Right]
7620-02 [Left]



Extra Leverage Femoral Neck Elevators

PRODUCT NO'S:
7650 [Standard]
7650-02 [Short Handle]

Designed by Wayne M. Goldstein, MD



Deep Cobra Retractors

PRODUCT NO'S:
6135 [Deep]
6135-L [Lighted Deep]

Designed by Wayne M. Goldstein, MD



Extra Large Hibbs Retractor

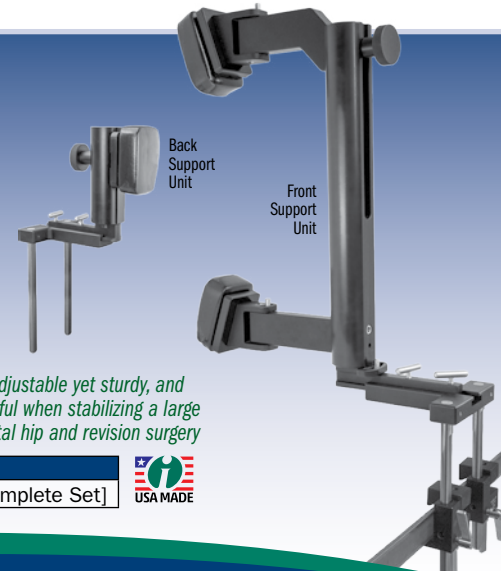
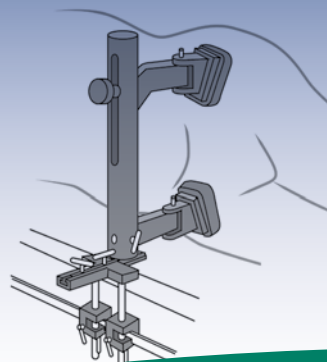
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